Title: Prosthetic Valves for Medical Application

Technical Field

The present invention relates to prosthetic valves for medical application. The valve of the present invention has been developed with special reference to a prosthetic heart valve, and therefore will be described with particular reference to this application. However, it will be appreciated that the valve of the present invention also could be used in other medical applications (e.g. as a venous valve).

Background Art

Prosthetic heart valves are used to replace a patient's own defective or damaged valves. Prosthetic heart valves currently in use are divided into two broad categories:- tissue valves and mechanical valves.

Tissue valves are either naturally-formed valves taken from pig hearts or valves formed from pericardium tissue taken from bovine hearts. In general, tissue valves are well accepted by the patient's body and require only the minimum anticoagulation treatment. However, tissue valves have the drawback that they wear out relatively rapidly, with a life of between 10 and 20 years.

Mechanical valves have excellent durability:- accelerated testing suggests that mechanical valves may have a life of the order of 200 years. However, mechanical valves have the drawback that they are not readily accepted by a patient's body and require long-term anticoagulation treatment to prevent thromboembolic complications. This is undesirable from the point of view of the patient's general health.

It is therefore an object of the present invention to provide a prosthetic valve, more particularly a heart valve, which has the durability of a mechanical valve but which is as compatible with the patient's body as a tissue valve, and thus requires no, or minimal, anticoagulation therapy.

Disclosure of Invention

The present invention provides a prosthetic valve in the form of a flap valve which includes at least one flap arranged to allow movement of liquid through the valve only

in one direction, the or each flap being made of a flexible openwork structure of a medically acceptable metal.

The valve may include only a single flap, which is arranged to close against a supporting wall, or two, three, or more flaps arranged to close against each other.

The flexible open work structure may be fabricated in any of a number of different ways, e.g. a knitted structure, a woven structure, a chainmail type of structure, or a fin flexible perforated plate.

Preferred materials are titanium or a medically approved titanium alloy such as the titanium/nickel alloy Nitenol ™. To be used for the knitted, woven, chainmail type of structures, the metal used must be capable of being drawn as a fine wire.

The valves with two or more flaps may be stented or stentless.

Brief Description of Drawings

By way of example only, a preferred embodiment of the present invention is described in detail, with reference to the accompanying drawings in which:-

Fig. 1 is a plan view of a tricuspid prosthetic heart valve in accordance with the present invention;
Fig. 2 is a view of the valve of Fig. 1 from below;
Fig. 3 is a side view taken along the line of Arrow III of the valve of Fig. 1;
Fig. 4 is a side view taken along the line of Arrow IV of the valve of Fig. 1;
Fig.s 5 a,b and c, are respectively side, plan and cross-sectional views of a unicuspid and valve in accordance with the present invention;
Fig.s 6a, b and c, are respectively side, plan and cross-sectional views of a bicuspid valve in accordance with the present invention; and
Fig.s 7 a,b,c and d show sections of knitted, woven, chainmail and perforated plate materials.

Best Mode for Carrying out the Invention

Referring to the drawings, a tricuspid prosthetic aortic valve 2 is basically similar in

construction to a tissue valve, i.e. it is a flap valve which consists of three equal size flaps 3,4,5 of substantially planar material, each flap being formed, in plan, as slightly larger than one-third of a segment of a circle. Thus, the flaps 3,4,5 can move apart to allow fluid to pass through the valve in the direction of Arrow A (Fig. 3), but the overlap of adjacent flaps closes the valve in the reverse direction.

Each flap 3,4,5 is made of a flexible openwork structure of a medically acceptable metal. As used herein, the term "medically acceptable" means a metal which is non-toxic to the body and preferably which is inert in the body, i.e. it does not provoke a "foreign body" reaction when implanted in the body. It is envisaged that the valve of the present invention would have the flaps 3,4,5 made from titanium or a medically approved titanium alloy (for example the nickel/titanium Nitenol (trademark) alloys), but other medically acceptable metals could be used.

A flexible openwork structure may be made from the wire, by using a knitting type of process (Fig. 7a) or by manufacturing chain mail (Fig. 7c) (i.e. a series of separate, interlocked rings of wire); a weaving type of process (Fig. 7b) also may be used. Another possibility is to use a thin, flexible plate formed with multiple holes (Fig. 7d). The finished openwork structure must be able to flex without permanently bending.

Woven flaps or perforated plate flaps provide a relatively stiff structure, whereas the chain mail structure provides a very flexible flap; the stiffness of a knitted structure is midway between that of the woven structure and that of the chain mail structure.

Titanium and titanium alloy wires are favoured because they are known to be not only inert when implanted in the body but also to promote good tissue growth. Further, evidence from titanium implants used in other areas (e.g. the mouth) suggests that infections can be cleared from a titanium surface more easily than from other foreign materials.

Each flap 3,4,5 has a curved outer edge 3a, 4a, 5a, from each end of which a side edge 6/7, 8/9, 10/11 extends inwards to meet the adjacent side edge as an acute angle, but with the apex between the side edges curved.

As shown in Fig.s 3 and 4, the outer edges 3a, 4a, 5a of each flap are curved in the side view, with the side edges 6/7, 8/9, 10/11 raised relative to the midpoint of the

outer edges. This increases the overlap between adjacent flaps where the adjacent side edges 6/8, 9/10 and 7/11 of the adjacent flaps overlap, and thus greatly reduces any risk of reverse flow through the valve (i.e. in the direction opposite to Arrow A).

The valve shown in the drawings is a semi-stented design, i.e. with a degree of reinforcing around the periphery of the valve, formed by a peripheral rib 13 which may simply be a thickened and/or reinforced area. The rib 13 is omitted from the views shown in Figures 3 and 4, for reasons of clarity.

The valve also may be produced as a fully stented valve, i.e. with the three flaps 3,4,5 mounted on a rigid annulus. Another possibility is to omit or reduce peripheral reinforcing altogether and produce the valve as a completely stentless valve; a stentless design (or one with a minimal stent) is advantageous for percutaneous insertion, i.e. by being inserted through the skin and then through a vein or an artery to the aorta. For percutaneous insertion, the valve has to be "scrunched" (i.e. folded in on itself) and a pronounced stent makes this impossible.

The tricuspid valve described above is the most common type of prosthetic valve, as it is in nature. However, it would be possible to form a valve in accordance with the present invention having more than three valve flaps, with the same general type of design as the tricuspid valve.

Unicuspid and bicuspid valves also are feasible; these are illustrated in figures 5 and 6 respectively.

Fig.s 5a,b and c show a unicuspid valve 15 which is circular in plan and has a peripheral annular stent 16. A rigid stationary wall 17 extends outwards from the stent, perpendicular to the plane of the stent, around approximately one third of the perimeter of the stent. A single flap 18 of flexible material is U-shaped in side view, and is secured around its lower margin 19 to the edges of the stationary wall 17. The flap 18 is dimensioned such that, when the flap 18 is pushed inwards towards the stationary wall 17, the upper margin 20 of the flap can press against the wall 17, preventing fluid from passing through the valve in the direction of Arrow A. Fluid passing through the valve in the direction of Arrow B tends to push the margin 20 of the flap away from the wall 17, so that fluid can pass freely in this direction.

The flap 18 is made from a flexible openwork structure as described with reference to the flaps 3,4,5 above. The wall 17 also is made of a medically acceptable metal and may be solid or openwork.

Fig.s 6a,b and c show a bicuspid valve 20 which is circular in plan and may be produced either as a stented or a stentless valve. In the stented version, the valve has a peripheral annular stent 21, which supports a rigid wall 22 which extends outwards from the stent, perpendicular to the plane of the stent. The shape of the wall 22 may be envisaged most easily as an open ended cylinder secured along its lower edge 23 to the stent 21 and with its upper edge (i.e. the edge furthest from the stent 21) formed with two opposed U-shaped cutouts, leaving opposed sides of the wall 22 formed with a U-shaped margin 25. Along the edges of the margin 25 on each side of the wall 22, valve flaps 24, made of a flexible openwork material, are secured. Each valve flap 24 is U-shaped in side view such that its lower edge fits the margin of the cutout portion of the wall 22, and the upper edge of the flap hangs over the central portion of the valve. Thus, fluid passing on the direction of Arrow X pushes the valve flaps 24 together, closing off the valve, but fluid in the direction of Arrow Y tends to push the flaps apart and can pass freely. The wall 22 may be made of solid or openwork material.

In the stentless version, the stent 21 and wall 22 are omitted and the valve consists simply of two U-shaped valve flaps 24 arranged as an opposed pair with their upper ends 26 secured together and their curved outer margins 25a slightly stiffened to maintain the correct shape of the valve, e.g. by a peripheral wire or peripheral ribbing. The stentless version operates in the same manner as the stented version.

The valve flaps 18 and 24 in the unicuspid and bicuspid versions may be made of any of the flexible openwork structures of medically acceptable metals described with reference to the tricuspid valve.

It is envisaged that the above described valve would be implanted in a patient with an initial coating over the flaps 3,4,5 of a degradable sealing material which would prevent leakage through the openwork structure of the flaps until such time as the patient's own system had developed its own coating over the flaps, by endothelisation.